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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/680,367	10/06/2003	Denise Demarais	19744P-000420US	4661

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EXAMINER

O CONNOR, CARY E

ART UNIT PAPER NUMBER

3732

DATE MAILED: 10/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/680,367	Applicant(s) DEMARAIS ET AL	
	Examiner Cary E. O'Connor	Art Unit 3732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-24 and 26-31 is/are rejected.
- 7) ☒ Claim(s) 25 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) ☒ Notice of References Cited (PTO-892) | 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) ☐ Notice of Informal Patent Application (PTO-152) |
| 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11/10/03</u> | 6) ☐ Other: ____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, line 5, "a lumen" appears to be a double recitation.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Omum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-9 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 6,660,014 in view of Imran (5,947,985). Although the conflicting claims are not identical, they are not patentably distinct from each other because it has been held that the omission of an element and its function is an obvious expedient if the remaining elements perform the

same function as before. In re Karlson, 136 USPQ 184 (CCPA 1963). Furthermore, the patented claims do not include an infusion port disposed to deliver an agent from the lumen to the interior of the cage. Imran shows a catheter for removing occlusive material comprising a catheter body 102 having a proximal end, a distal end, a lumen therethrough, and a macerator 103 located near the distal end. Ports 111 are located within the macerator to deliver irrigation liquid to the area of the macerator. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the catheter body with ports in the area of the cage, in view of Imran, so irrigation liquid can be supplied to the clot area.

Claims 15-24 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 6,660,014 in view of Farhat (5,556,408). Although the conflicting claims are not identical, they are not patentably distinct from each other because it has been held that the omission of an element and its function is an obvious expedient if the remaining elements perform the same function as before. In re Karlson, 136 USPQ 184 (CCPA 1963). Furthermore, the patented claims do not include means within the body for aspirating material disrupted by the macerator. Farhat shows a catheter for removing occlusive material 24 from a body lumen wherein the catheter body includes means within the body for aspirating material disrupted by the cutter. This feature ensures that all loose material is removed from the body lumen. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the catheter with

means within the body for aspirating material disrupted by the macerator, as taught by Farhat, in order to ensure that all loose material is removed from the body lumen.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 26, 27, 29 and 30 are rejected under 35 U.S.C. 102(e) as being anticipated by Thomas et al (5,904,698). Thomas shows a catheter 10 for removing occlusive material 24 from a body lumen 22 comprising a catheter body 12 having a proximal end 16, a distal end 18 and a lumen there through. A radially expandible positioning cage 32 is located near the distal end of the catheter body. A macerator 48 configured to break up occlusive material is located in the cage. The catheter also includes means for selectively adjusting the diameter of the cage (see column 6, last paragraph).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 4, 6-8, 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thomas et al (5,904,698) in view of Imran (5,947,985). Thomas shows a catheter 10 for removing occlusive material 24 from a body lumen 22 comprising a catheter body 12 having a proximal end 16, a distal end 18 and a lumen therethrough. A radially expansible positioning cage 32 is located near the distal end of the catheter body. A macerator 48 configured to break up occlusive material is located in the cage. Thomas does not include an infusion port disposed to deliver an agent from the lumen to the interior of the cage. Imran shows a catheter for removing occlusive material comprising a catheter body 102 having a proximal end, a distal end, a lumen therethrough, and a macerator 103 located near the distal end. Ports 111 are located within the macerator to deliver irrigation liquid to the area of the macerator. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the catheter body of Thomas with ports in the area of the cage, in view of Imran, so irrigation liquid can be supplied to the clot area. As to claims 2 and 4, note that the catheter also includes means for selectively adjusting the diameter of the cage (see column 6, last paragraph). As to claim 6, the expanded and unexpanded dimensions of the cage and macerator are considered to have been obvious design choices to one of ordinary skill in the art, depending on the individual circumstances of the procedure.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Thomas et al (5,904,698) in view of Imran (5,947,985) as applied to claim 1 above, and further in view of Gunther (5,330,484). Gunther shows a catheter for removing occlusive material 24 from a body lumen 22 comprising a catheter body 1 having a proximal end, a distal end and a lumen there through. A radially expansible positioning cage 7 is located near the distal end of the catheter body. A macerator 6 configured to break up occlusive material is located in the cage. The cage is self-expanding and has a predetermined unconstrained diameter. It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the cage of Thomas of a self-expanding material, in view of Gunther, in order to eliminate the expansion mechanism and provide a slimmer catheter.

Claims 5 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thomas et al (5,904,698) in view of Imran (5,947,985) as applied to claims 1 and 9 above, and further in view of Resseman et al (5,540,707). Ressemann shows a catheter for removing occlusive material from a body lumen comprising a self-expanding macerator and a drive unit at the proximal end of the catheter body. It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the macerator of Thomas as modified by Imran of a self-expanding material and provide the catheter with a drive unit connected to the macerator, in view of Ressemann, in order to make expansion and rotation of the macerator easier.

Claims 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thomas et al (5,904,698) in view of Strauss et al (6,066,152). Thomas teaches a

method comprising the all the claimed steps except for the step of releasing a thrombolytic agent through the catheter to the region of thrombus. Strauss teaches a method for removing a thrombus comprising macerating the thrombus (column 6, lines 39-42) and delivering a thrombolytic agent to the thrombus which helps to dissolve the thrombus. It would have been obvious to one of ordinary skill in the art at the time the invention was made to deliver a thrombolytic agent to the thrombus site of Thomas, as taught by Strauss, in order to further aid in removal of the thrombus and increase efficiency of the catheter.

Claims 15, 16, 18, 20-22 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thomas (5,904,698) in view of Farhat (5,556,408). The catheter of Thomas does not show means within the body for aspirating material disrupted by the macerator. Farhat shows a catheter from removing occlusive material 24 from a body lumen wherein the catheter body includes means within the body for aspirating material disrupted by the cutter. This feature ensures that all loose material is removed from the body lumen. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the catheter of Thomas with means within the body for aspirating material disrupted by the macerator, as taught by Farhat, in order to ensure that all loose material is removed from the body lumen.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Thomas et al (5,904,698) in view of Farhat (5,556,408) as applied to claim 15 above, and further in view of Gunther (5,330,484). Gunther shows a catheter for removing occlusive material 24 from a body lumen 22 comprising a catheter body 1 having a proximal end,

a distal end and a lumen there through. A radially expansible positioning cage 7 is located near the distal end of the catheter body. A macerator 6 configured to break up occlusive material is located in the cage. The cage is self-expanding and has a predetermined unconstrained diameter. It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the cage of Thomas of a self-expanding material, in view of Gunther, in order to eliminate the expansion mechanism and provide a slimmer catheter.

Claims 19 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thomas et al (5,904,698) in view of Farhat (5,556,408) as applied to claims 15 and 22 above, and further in view of Resseman et al (5,540,707). Ressemann shows a catheter for removing occlusive material from a body lumen comprising a self-expanding macerator and a drive unit at the proximal end of the catheter body. It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the macerator of Thomas as modified by Imran of a self-expanding material and provide the catheter with a drive unit connected to the macerator, in view of Ressemann, in order to make expansion and rotation of the macerator easier.

Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Thomas (5,904,698). The expanded and unexpanded dimensions of the cage and macerator are considered to have been obvious design choices to one of ordinary skill in the art, depending on the individual circumstances of the procedure.

Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Thomas et al (5,904,698) in view of Ressemann et al (5,540,707). Ressemann shows a catheter

for removing occlusive material from a body lumen comprising a self-expanding macerator and a drive unit at the proximal end of the catheter body. It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the macerator of Thomas of a self-expanding material and provide the catheter with a drive unit connected to the macerator, in view of Ressemann, in order to make expansion and rotation of the macerator easier.

Claim Objections

Claims 1 and 15 is objected to because of the following informalities: In claim 1, line 5, "t" should be changed to -- to --. In claim 15, line 7, "for" (first occurrence) should be deleted. Appropriate correction is required.

Allowable Subject Matter

Claim 25 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

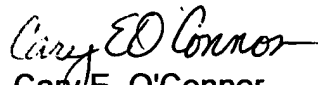
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cary E. O'Connor whose telephone number is 703-308-2701. The examiner can normally be reached on M-Th 7:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached on 703-308-2582. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Cary E. O'Connor
Primary Examiner
Art Unit 3732

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